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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,466	01/26/2004	Sachiko Machida	690115.401C1	8356

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,466	MACHIDA ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *18-31,33 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,32,34 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and arguments filed 13 July 2005 have been entered. Claims 2-7, 11-13, 32, 34, 36 and 38 are currently amended. Claim 39 is canceled. Claims 18-31, 33 and 35 are withdrawn from consideration. Claims 1-38 are currently pending in this application.

Withdrawn Rejections

2. Previous rejection of claims 1-17, 32, 34 and 36-39 under 35 USC 102(e) have been withdrawn.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 2-14, 32, 34 and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite a product made by a process and it is unclear whether these processes provide product limitations that further limit the product of claim 1. Claims 2-14, 32, 34 and 36-38 do not appear to provide product limitations that further limit the product of claim 1. Therefore prior art teaching the receptor chip of claim 1 would be capable of comprising the product limitations of claims 2-14, 32, 34 and 36-38 and would encompass the product of the claims.

Claim 17 is drawn to a receptor chip that is adapted for detection using a particular method, but it is unclear how the adaptation affects the product structure of claim 1. It is unclear whether the adaptation for a specific detection method requires any further product limitations.

Claim Rejections - 35 USC § 102

4. Claims 1-15, 32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Holtzman et al. (US 2002/0055139).

Holtzman et al. teach a receptor chip (96 well plates, par. 698) on which a recombinantly expressed receptor protein (TANGO 402 proteins can be used as receptors for Ox-LDL, par. 92) is immobilized via factor capable of specifically binding to biotin (par. 698).

Regarding claim 15, Holtzman et al. teach the receptor protein able to bind to Ox-LDL, which therefore makes the receptor protein part of a LDL receptor related protein family (par. 92).

Regarding the limitations of claims 2-14, 32 and 36, these claims recite a product formed by a process, and do not provide specific product limitations for the receptor chip. Therefore it is unclear what specific limitations are required for the receptor chip. Since Holtzman et al. teaches the product limitations recited in claim 1, the chip of Holtzman et al. is capable of providing the limitations of claims 2-14, 32 and 36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 16, 34, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holtzman et al. (US 2002/0055139), as applied to claims 1 and 32, in view of Moriwaki et al. (Arterioscler Thromb Vasc Biol 1998 18: 1541-1547).

Holtzman et al. teach a receptor chip comprising immobilized receptor protein of the LDL receptor related protein family, but do not teach the receptor protein being LOX-1.

Moriwaki et al. teach a receptor protein of LOX-1 (pg. 1545, left column, section: *LOX-1 binds to protein moiety of Ox-LDL*), in order to define ligand specificities of LOX-1.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to immobilize on the receptor chip of Holtzman et al., a receptor protein of LOX-1 as taught by Moriwaki et al., in order to provide a more efficient testing surface by accommodating automation of the assay and facilitating separation of complexed and uncomplexed forms of LOX-1.

Regarding the limitations of claims 34, 37 and 38, these claims recite a product formed by a process, and do not provide specific product limitations for the receptor chip. Therefore it is unclear what specific limitations are required for the receptor chip. Since Holtzman et al. teaches the product limitations recited in claims 1 and 32, the chip of Holtzman et al. is capable of providing the limitations of claims 34, 37 and 38.

2. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holtzman et al. (US 2002/0055139), as applied to claim 1, in view of Duffy et al. (US 2003/0032076).

Holtzman et al., teach a receptor chip comprising an immobilized receptor protein, but fail to teach the receptor chip adapted for detection by mass spectrometry.

Duffy et al. teach adapting a surface (par. 186) for use with ELISA or SPR (par. 186), in order to detect molecules.

It is well known in the art, as evidenced by Duffy et al., that ELISA detection is functionally equivalent to SPR detection, and the same adapted substrate can be used for both ELISA and SPR detection. It would have been obvious to substitute the SPR detection, as taught by Duffy et al., for the ELISA detection taught by Holtzman et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent detection technique since the expected measurement effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill based on the economics and availability of detection equipment.

Response to Arguments

3. Regarding the rejection of claims 2-14, 32, 34 and 36-38 under 35 USC 112, second paragraph, applicant's argue that claim 32 recites a product by process and no longer depends from withdrawn claims. However, it is still unclear what product limitations are required for the receptor chip of claim 32. It is unclear if the final product has the same product limitations as claim 1. It is unclear what product limitations are provided by each step of the method of making. Applicant further argues that adaptation of the chip for techniques is clear because an appropriate dielectric and/or metal layer may be utilized for SPR detection. However, such limitations are not claimed in claim 17, and it is unclear if any surface may be used for detection with surface plasmon resonance, quartz-crystal microbalance or mass spectrometry.

4. Applicant's arguments with respect to claims 1-17, 32, 34 and 36-39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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09/27/05